Attorney Docket No.: 2001_1102A Application No.: 09/890,688

May 28, 2004

REMARKS

I. CLAIM STATUS & AMENDMENTS

Claims 1-9 were pending in this application when last examined. Claims 2-6 and 8 have been examined on the merits, and stand rejected. Claims 1, 7, and 9 are withdrawn as non-elected subject matter.

The present amendment amends claims 2, 3, 5, 6, and 8.

The present amendment cancels claim 4 without prejudice or disclaimer thereto.

Applicants reserve the right to file a continuation or divisional application on any canceled subject matter.

Claims 1-3 and 5-9 are now pending in this application.

Claims 2, 3, 5, 6, and 8 were amended to better conform with U.S. claim practice and to encompass the elected subject matter as suggested by the Examiner. Support for these changes can be found in the claims as originally filed, and throughout the Specification.

Therefore, no new matter has been added by this amendment.

II. CLAIM OBJECTIONS

Claims 2-6 and 8 are objected to for containing non-elected subject matter, and for depending on non-elected claims. See Office Action, page 4, item 7.

The claims have been amended to encompass the elected subject matter as suggested by the Examiner, thereby obviating this objection.

III. OBJECTION TO THE SPECIFICATION

The Specification has been objected for not referring to Figures 6-1, 10-1, 10-2, and 35-1. See Office Action, page 5, item 8.

The Specification has been amended to include the appropriate references to Figures 6-1, 10-1, 10-2, and 35-1, thereby obviating this objection.

IV. OBJECTION TO THE TITLE

The Title has been objected to as non-descriptive. See Office Action, page 5, item 9.

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A new, more descriptive title replaces the original title, thereby obviating this objection.

V. REJECTIONS UNDER 35 U.S.C. §§ 101 AND 112, UTILITY AND ENABLEMENT

Claims 2-6 and 8 stand rejected under 35 U.S.C. §101, because the claimed invention allegedly lacks utility. Consequently, these same claims are also rejected under 35 U.S.C. § 112, first paragraph, as the Specification allegedly lacks an enabling disclosure for how to use the claimed invention. See Office Action, pages 5-14, items 11 and 13.

Applicants respectfully traverse these rejections for the following reasons.

The Specification discloses both a credible "well-established utility" and a credible "asserted utility" for the claimed nucleotide sequence encoding the protein of SEQ ID NO: 2, the claimed nucleotide sequence of SEQ ID NO: 1 and its expression vector.

To satisfy the utility requirement under 35 U.S.C. § 101, the claims and the Specification must disclose either a credible "well-established utility" or a credible "asserted utility" for the claimed invention. M.P.E.P. § 2107.02.

A "well established utility" is a specific, substantial, and credible utility that must be immediately apparent to one skilled in the art based on the characteristics of the invention (e.g., properties or applications of a product or process). M.P.E.P. § 2107; Guidelines for Examination of Applications for Compliance With the Utility Requirement, 66 Fed. Reg. 1097, 1098 (Jan. 5, 2001). In other words, it must be well known, immediately apparent and implied by the specification based on the disclosure of the properties of the claimed invention, either alone or taken with knowledge of one skilled in the art.

In the instant case, the Specification satisfies the requirements for a "well established utility." The Specification in Example 1 on page 20, line 10 to page 21, line 13 discloses the function of the of the claimed invention. Specifically, the cDNA clone HP02573 encodes a human protein that is a human homologue of the bacterial GTP-binding protein CgpA. As noted at page 21, lines 12-13, GTP-binding proteins play an important role in intracellular signal transduction. Thus, one of skill in the art, upon reading the Specification, would reasonably believe that the present invention has the structure and function of a GTP-binding protein CgpA.

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Furthermore, it is well established that bacterial GTP-binding protein CgpA are essential for cell viability and are present at levels throughout the cell cycle as discussed in Maddock et al (Journal of Bacteriology, Vol. 179, No. 20, pp. 6426-6431 (1997)). This reference was made of record in the last Office Action. Although Maddock and the other cited references utilized in the last Office Action characterize CgpA as a minor protein, these reference clearly indicate that the protein is *essential for cell viability* and is *present in levels throughout the cell cycle*. Since instant invention is a human homologue of the GTP-binding protein CgpA, it too is essential for cell viability and is present in levels throughout the cell cycle.

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Furthermore, the Specification discloses the generation and use of antibodies to the protein of the present invention. Thus, one of skill in the art would also reasonably believe that the claimed nucleic acid, the protein it encodes and the antibody specific for it are useful as diagnostic reagents and/or a laboratory reagents for analyzing cell viability and/or for studying intracellular signal transduction. For instance, the claimed nucleotide sequence could be used as nucleic acid hybridization probe to analyze cell viability. This satisfies the requirement of a well-established utility.

Moreover, the Specification further asserts such specific utilities at page 2, lines 11-17. Accordingly, the skilled artisan, upon reading the disclosure, could use the protein of the instant invention to develop and screen for medicinal compounds following routine procedures.

No evidence has been presented to directly contradict such a well established and specifically asserted utilities.

Nonetheless, the rejection indicates that this utility does not define a "real world" use, because it allegedly amounts to basic research, such as studying the properties of the claim product itself or the mechanisms in which the material is involved. The rejection also sets forth four journal articles as allegedly providing support for the position that the function and use of the bacterial GTP-binding protein CgpA from *Caulobacter crescentus* is unknown. However, it is well established that diagnostic antibodies and other laboratory reagents are well known and widely used in the biotechnology and pharmaceutical industry as reagents for research, diagnostic and therapeutic purposes. In this regard, they have "real world use" and are afforded patent protection.

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Therefore, in view of the above, it is evident that the Specification describes at least one credible utility. Thus, the rejections of claims 2-6 and 8 under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph, are untenable and should be withdrawn.

REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH, WRITTEN DESCRIPTION VI.

Claims 2, 5, 6 and 8 are rejected under 35 U.S.C. §112, first paragraph, because the Specification allegedly lacks written description for the genomic DNA encoding the protein of SEQ ID NO: 2. See Office Action, pages 14-16, item 14.

The present amendment is deemed to overcome this rejection, because it removes the fragments language and specifies the elected SEQ ID NOs. Thus, the rejection of claims 2, 5, 6 and 8 under 35 U.S.C. §112, first paragraph, for lack of written description is untenable and should be withdrawn.

CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is now in condition for allowance and early notice to that effect is hereby requested.

If it is determined that the application is not in condition for allowance, the Examiner is invited to telephone the undersigned attorney at the number below if he has any suggestions to expedite allowance of the present application.

Respectfully submitted,

THE COMMISSIONER IS AUTHORIZED TO CHARGE ANY DEFICIENCY IN THE FEES FOR THIS PAPER TO DEPOSIT ACCOUNT NO. 23-0975

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